

Docket No.: 022719-0023RCE  
(PATENT)

**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Patent Application of:  
David D. Konieczynski et al.

Application No.: 10/092,954

Filed: March 6, 2002

For: CONVECTION-ENHANCED DRUG  
DELIVERY DEVICE AND METHOD OF USE

Confirmation No.: 7357

Art Unit: 3763

Examiner: R. Maiorino

MS Appeal Brief – Patents  
Commissioner for Patents  
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June 21, 2006

Date of Deposit

  
By: William C. Geary III

**REPLY BRIEF**

Dear Sir:

This is in reply to the new points of argument raised in the Examiner's Answer mailed April 21, 2006. Appellants respectfully request that the arguments presented below be considered in connection with this appeal.

## **I. Introduction**

In response to Appellant's Appeal Brief the Examiner has withdrawn certain grounds of rejection. Thus, only a single ground of rejection remains.

Claims 1, 3, 7, 8, 10, 11, 14-17, 19, 20, 22, 25, and 28-40 are currently pending, all of which stand rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Publication No. 2004/0034332 of Uhland.

## **II. Uhland Does Not Disclose Each Element of Appellant's Claimed Invention**

The Examiner has failed to establish that Uhland discloses all of the limitations of Appellant's claims. In response to Appellant's arguments regarding Uhland, the Examiner states, on page 5 of the Examiner's Answer:

“...clearly the term “target tissue” is broad enough to include implanting the distal (outlet) end of the micropump in any area of the body.”

The Examiner argues that a “target tissue” is broad enough to encompass delivering a drug to any area of the body, regardless of whether that area is the actual target of the drug being delivered. This is not an accurate assessment of the phrase “target tissue,” and the Examiner overlooks certain aspects of claim 1 when making this argument.

Independent claim 1 requires that the fluid delivery line be effective to extend from the fluid outlet to a discharge portion positionable at a *target tissue site*. Further, the pump must be effective to deliver a carrier fluid to the fluid outlet such that a drug material is discharged at the *site of a target tissue* in order to *treat* that target tissue. The effect of this limitation is to require that the pump and its discharge outlet be configured and effective to release the drug at a tissue site that is to be treated.

Uhland is entirely different in that it only teaches or suggests using a drug delivery pump for use with drugs, such as pain medication or insulin, that are delivered generally to a non-specific site in the body. These drugs are not delivered to a target tissue *to treat* that target tissue, but rather are

released into the body, often subcutaneously, and diffused through the body to effect treatment at a tissue site that is remote from the delivery site.

### III. Uhland is an Inadequate Disclosure

The specification of a patent must enable a person skilled in the art to make or use the invention without undue experimentation. In Uhland, the teaching regarding implantable pump is extremely limited, and merely states:

In another embodiment, a microchip device is incorporated into an implantable micropumping system, for example for the delivery of drugs over extended periods of time, such as is needed the delivery of insulin to diabetics and treating certain kind of severe chronic pain. Micropump apparatus suitable for use in these devices are known in the art (see, e.g., U.S. Pat. No. 4,596,575 to Rosenberg). The micropump pumps carrier fluid across one or more surfaces of the microchip device. A variety of carrier fluids can serve as the pumped fluid, including, but not limited to, filtered extra-cellular fluid, saline solution, or water.

In a preferred embodiment, release of doses is actively controlled, such as by disintegration of reservoir caps via electrochemical dissolution, as described in U.S. Pat. No. 5,797,898 and No. 6,123,861 to Santini. The release system preferably is in the form of a solid that is soluble in the carrier fluid. As the fluid passes over or around the activated and opened reservoir, the solid drug dissolves in the carrier fluid, forming a solution that is pumped into the extra-cellular environment.

Uhland, paragraphs 108 and 109.

The Examiner asserts, on page 4 of the Examiner's Answer, that "Figure 8A of Uhland readily shows how any micropump can be used to assembly an apparatus implantable into the body. It is simply a matter [of] installing the controlled release drug assembly downstream from the pump." This is incorrect as Figure 8A of Uhland only illustrates an intravenous drug delivery system that exists outside of the body of a patient. There is no teaching in Uhland that explains how the *external IV system* illustrated in Figure 8A could be altered or reconfigured to be used as an implantable device. The Examiner's argument ignores this fact and actually pretends that Uhland's discloses an implantable pump system in the course of discussing Figure 8A.

To the extent that Uhland makes any mention of an implantable pump system the teaching is scant and deficient. In fact the limited disclosure, which is quoted above, relies on the Rosenberg reference (mentioned in paragraphs 108 and 109 of Uhland). The Examiner argues in the Examiner's Answer that "the Rosenberg reference is not even required to show how such a system could be operative. It is cited merely to exemplify that micropumps are known in the art." Appellants respectfully disagree. The only teaching of how a micropump would be configured and function would have to be found in Rosenberg, as Uhland does not adequately disclose the working of such a device, as discussed above. Because Uhland alone is not sufficient to anticipate Appellant's invention, the Rosenberg reference would be needed to supplement the discussion of a micropump found in paragraphs 108 and 109 of Uhland.<sup>1</sup>

### III. Conclusion

For the reasons noted above, Appellant submits that the pending claims define patentable subject matter. Accordingly, Appellant requests that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Dated: June 21, 2006

Respectfully submitted,

By 

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<sup>1</sup> The Appeal Brief, at pages 6-7, explains the inadequacy of Rosenberg.